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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,307	03/21/2001	Naoto Oku	50026/024001	2668

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BOSTON, MA 02110

EXAMINER

ASHEN, JON BENJAMIN

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/623,307

Applicant(s)

OKU ET AL.

Examiner

Jon B. Ashen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-81 is/are pending in the application.
- 4a) Of the above claim(s) 64-81 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 53-56 and 58-60 is/are allowed.
- 6) ☒ Claim(s) 51, 52, 57 and 61-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 August 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

1. Claims 51-81 are pending in the instant application. Claims 51 and 52 are currently amended. Claims 53-63 are previously presented and were found allowable in the Office action mailed 2/24/2004. Claims 64-81 are newly presented.

2. Newly submitted claims 64-81 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Inventions that are a) a composition comprising a polyethylenimine or a salt thereof, wherein said polyethylenimine has a repeat unit represented by formula V (as depicted in claims 51 and 52) and b) a composition comprising a polyalkylenimine or salt thereof wherein said polyalkylenimine comprises two or more tetraethylenepentamine or spermine structures, two or more hydrophobic groups and a degree of alkylation of less than or equal to 24.5% are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and will each have a different effect.

Although each of the inventions operates by complexing to a negatively charged substance (for example, an oligonucleotide) to facilitate transport of said substance into cells, each composition is distinct. Each composition upon

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delivering a negatively charged substance, for example, an oligonucleotide capable of modulating gene expression, will have a different effect on said gene expression based on the efficiency of delivery, said efficiency depending on the structure of the polyethylenimine or polyalkylenimine carrier of the invention, as shown in Applicant's examples 17, 22 and 23, Tables 1, 3 and 4.

Furthermore, searching both of the inventions a) and b) as set forth above, would impose a serious search burden. In the instant case, prior art searches of a) polyethylenimine that has a repeat unit represented by formula V and b) polyalkylenimine comprising two or more tetraethylenepentamine or spermine structures are not coextensive. Search of each of these inventions requires different structure searches as well as different searches of key words related to each structure from the patent and non-patent literature databases, including subsequent in-depth analysis of unrelated prior art literature, placing a serious burden on the Office in terms of both search and examination of the unrelated prior art. As such, it would be burdensome to perform examination of these inventions together.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 64-81 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Drawings

3. The drawings are objected to because Figures 7 and 8 both depict Nitrogen with a valence of 4 with an N atom in the center of each figure that is clearly bound to N, N, R and H. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 51, 52, 57 and 61-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 51 and 52 are drawn to compositions comprising polyethylenimine wherein said polyethylenimine has a repeat unit represented by formula (V). Claims 57 and 61 are rejected as being dependent on claim 51, claims 62-63 are rejected as being dependent on claim 61, for the same reasons as set forth herein. In the instant case, claims 51 and 52 depict the formula (V) as containing nitrogen with a valence of 4 (as opposed to either 3 or 5), showing an N atom in the center of each figure that is clearly bound to N, N, R and H. In the instant case, the subject matter that applicant regards as their invention is not particularly pointed out or distinctly claimed because it is any person of ordinary skill in the art cannot determine what specific substituents should be present on the nitrogen in claims 51 and 52. In any amendment to claims 51 and 52, Applicant should identify, with particularity, where the support for such an amendment is found in the specification and additionally, guard against the introduction of new matter.

Conclusion

6. Claims 51-63 remain allowable over the prior art searched.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history

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information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jba



JOHN L. LeGUYADER
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